UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. BARRY J. CADDEN, et al., Defendants.	)	Court No.: 14-cr-10363-RGS

GOVERNMENT'S MOTION FOR RECONSDIERATION OF COURT'S ORDERS DISMISSING COUNTS 96-98, 101-109 OF THE INDICTMENT

The United States of America hereby respectfully requests that this Court reconsider its orders (Doc. Nos. 675 and 678) dismissing counts 96-98 and 101-109 of the Indictment, charging defendants Kathy S. Chin ("Chin"), Michelle L. Thomas ("Thomas"), and Alla V. Stepanets ("Stepanets") (collectively, "the defendants") with violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"). The Court's conclusion that the defendants were not dispensing drugs under the FDCA is incorrect as a matter of law, and relies on an overly narrow and incorrect reading of the statute. The Indictment in fact adequately charges the defendants with violating the FDCA, and puts them on notice of what they are accused of doing in violation of that act. Furthermore, the Court's orders rely on incorrect assumptions about the government's evidence. The government's evidence at trial would establish that all three defendants, who for the counts charged were the *only* pharmacists who reviewed the orders before NECC shipped them to customers, were knowingly dispensing medication pursuant to invalid prescriptions with the intent to defraud or mislead. Accordingly, the government requests that this Court reconsider its orders and reinstate the charges against the defendants.

FACTUAL BACKGROUND

It is well-settled that "the government need not put forth specific evidence to survive a motion to dismiss." United States v. Ngige, 780 F.3d 497, 502 (1st Cir. 2015). Instead, as the First Circuit has explained, "[w]hen a defendant seeks dismissal of an indictment, courts take the facts alleged in the indictment as true, mindful that the question is not whether the government has presented enough evidence to support the charge, but solely whether the allegations in the indictment are sufficient to apprise the defendant of the charged offense." Id.; see also United States v. Geurrier, 669 F.3d 1, 4 (1st Cir. 2011) ("Consistent with that rule, courts routinely rebuff efforts to use a motion to dismiss as a way to test the sufficiency of the evidence behind an indictment's allegations."); United States v. DeLaurentis, 230 F.3d 659, 661 (3d Cir. 2000). ("The government is entitled to marshal and present its evidence at trial, and have its sufficiency tested by a motion for acquittal pursuant to Federal Rule of Criminal Procedure 29."). A court should not "look[ ] beyond the facts of the indictment and dr[a]w inferences as to the proof that would be introduced by the government at trial." United States v. Alfonso, 143 F.3d 772, 776 (2d Cir. 1998).

The government submits that the Court did precisely that by adopting the defendants' descriptions of their job responsibilities in reaching its conclusion to dismiss these counts. Therefore, the government offers the following brief facts (which are just some of those that would be offered at trial) as illustrative of the dangers inherent in making, as the Court did here, any assumptions about the facts beyond those in the Indictment at this stage. The government does so without in any way waiving its argument that in evaluating a motion to dismiss, a court is not to consider factual submissions or evaluate evidentiary sufficiency. See id. 776-777 ("Unless the government has made what can fairly be described as a full proffer of the evidence it intends to present at trial…the sufficiency of the evidence is not appropriately addressed on a pretrial motion to dismiss an indictment").

The Indictment alleges the defendants Chin, Thomas, and Stepanets were licensed pharmacists in the Commonwealth of Massachusetts, and were employed at New England Compounding Pharmacy, Inc., doing business as New England Compounding Center ("NECC"). Under Massachusetts law, only licensed pharmacists are permitted to dispense prescription medication. See Mass. Gen. Laws ch. 112, § 30. Licensed pharmacists are also responsible for the actions of any support personnel working in the pharmacy. Id.

At trial, the government's evidence will demonstrate that prescription drugs were dispensed at NECC through a multi-step process in which the defendants played an integral and important role. First, drug orders came into NECC through fax machines located in the order processing area. The drug orders were submitted by customers on NECC's "Prescription Order Form." Upon receipt of the orders, NECC staff (comprised of pharmacy technicians or other trained employees) would pull the file for each customer and contact the customer to confirm the orders.[1] NECC's regular stock drugs, such as betamethasone, triamcinolone, and methylprednisolone acetate, were filled into vials of various sizes in NECC's clean room and stored in bins in the order processing area at NECC. NECC staff in the order processing area would pull the requisite number of pre-filled vials for each order from the bins on the shelves and place them together with the Prescription Order Forms.

The Prescription Order Forms submitted by customers, along with the actual drugs needed to fill the orders, would then be given to data-processing employees who would input information into NECC's electronic database, including the names of patients and the name and amount of the

[1] In addition to her work as a checking pharmacist, defendant Stepanets confirmed orders as well.

drugs ordered. At that point, a "prescription" for each patient name would be generated to be held on file at NECC, along with a "prescription" label that was affixed to a Mylar bag in which the drugs would eventually be packaged. Both the "prescriptions" that NECC's data-processing staff created and held on file, and the "prescription" labels affixed to the Mylar bags in which the drugs were placed, carried the following warning: "Caution: Federal law prohibits transfer of this drug to any other person than patient for whom prescribed." Following the creation by data-processing staff of "prescriptions" and "prescription" labels, the orders were given to the processing supervisor, who generated an invoice, packing list, and shipping label.

After these documents were generated by the data-processing staff, the Prescription Order Form, the drugs, the "prescription" labels affixed to Mylar bags, and the shipping documents were sent to the defendants to be checked. The defendants were *the only pharmacists* to review the drug orders prior to shipment. Acting in their official capacities as licensed pharmacists, the defendants verified the orders and approved the drugs for shipment, thereby causing them to be dispensed. In fact, the drugs could not be shipped by NECC until a pharmacist checked the entire order for accuracy, much the same way a pharmacist checks an order put together by another staff member at a retail pharmacy. The defendants filled this role at NECC, and indicated their approval for the dispensing of the medications on forms entitled, "Pharmacist's Rx Order Verification Sheet." Following the defendants' approval that the order could be dispensed, the drugs were given to shipping employees who packaged them for shipment to customers.[2]

---

[2] The process for custom (as opposed to stock) drug orders was essentially the same, but rather than having NECC data-processing staff pull the pre-filled vials out of the bins in the order processing area, they would send a request into the clean room to compound the custom-ordered drugs. The customer orders would otherwise continue to be processed in the usual manner by the data processors and the processing supervisor. Once the Prescription Order Form, the prescription labels affixed to Mylar bags, and the shipping documents were sent to the defendants, the defendants were responsible for putting together and reviewing the orders with the drugs that were sent out of the clean room on a conveyor belt.

The Indictment alleges that on four separate occasions in 2011 and 2012, defendant Chin, with the intent to defraud and mislead, caused drugs to be dispensed from NECC without valid prescriptions. Indictment (Doc. No. 1) at 56, 58-59 (Dec. 16, 2014). Specifically, defendant Chin checked orders and approved drugs to be dispensed for patients supposedly named John Stewart, Craig Killborne, David Letterman, Jay Leno, Jimmy Kimmel, Al Bundie, Johnny Knoxville, Dick Van Dike, Mike Myers, Bella Swan, Flash Gordon, Long John, Tony Tiger, and Chester Cheeto, among others. Id. at 58-59. The Indictment further alleges that on two occasions in 2012, defendant Thomas, with the intent to defraud and mislead, also caused drugs to be dispensed from NECC without valid prescriptions. Id. at 56, 59. Specifically, defendant Thomas checked orders and approved drugs to be dispensed for patients supposedly named L.L. Bean, Filet O'Fish, Rug Doctor, Squeaky Wheel, Coco Puff, Harry Potter, Mary Lamb, and Ginger Rogers, among others. Id. at 59. Lastly, the Indictment alleges that on seven separate occasions spanning from 2010 through 2012, defendant Stepanets caused drugs to be dispensed from NECC without valid prescriptions. Id. at 56-59. Specifically, defendant Stepanets checked orders and approved drugs to be dispensed for patients supposedly named Wonder Woman, Fat Albert, Robert Redford, Bud Weiser, Silver Surfer, Jimmy Carter, Bill Clinton, and Donald Trump. Id. at 57-58.

With this understanding of the defendants' important role within NECC's dispensing process, the government next turns to the arguments outlined in this Court's Memorandum and Order on Defendants' Motion to Dismiss (Doc. No. 675) [hereinafter "the Order"].

LEGAL ARGUMENT

I. To the Extent that the Order Concluded that the Defendants Were Not Dispensing as a Matter of Law, the Court Erred.

A. The Order's Limited Interpretation of the Term "Dispensing" Is Overly Restrictive and Contrary to Law and Pharmacy Practice.

1. The Order's Dispensing Interpretation Conflicts with the Purposes of the Statute and Case Precedent.

The United States Supreme Court has explained that courts "must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health…." United States v. Article of Drug…Bacto-Unidisk…, 394 U.S. 784, 798 (1969). "The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely a collection of English words." United States v. Dotterweich, 320 U.S. 277, 280 (1943).

Applying this broad reading of the FDCA, the Supreme Court in Dotterweich addressed the reach of criminal liability under the FDCA in the context of persons working at a corporation distributing misbranded drugs:

> Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission – assuming the evidence warrants it – to the jury under appropriate guidance. *The offense is committed…by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs*…Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather

> than to throw the hazard on the innocent public who are wholly helpless.

Id. at 284 (emphasis added). The Supreme Court declined to identify specifically the class of persons responsible for furthering a misbranded drug transaction, instead leaving such definitions to "the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries." Id.

In light of the Supreme Court's guidance, numerous courts have routinely applied a broad reach to the class of individuals covered under the FDCA's "dispensing" language. See e.g., United States v. Ikejiani, 630 Fed. Appx. 933, 938 (11th Cir. 2015) (upholding conviction of pharmacist who dispensed medication as a drug wholesaler); United States v. Arlen, 947 F.2d 139, 147 (5th Cir. 1991) (upholding conviction of bodybuilder who dispensed anabolic steroids through the mail to users and other dealers); De Freese v. United States, 270 F.2d 730, 736-37 (5th Cir. 1959) (affirming conviction of physician who dispensed drugs in bulk for resale by others); United States v. Oz, 2016 WL 1183041, at *10 (D. Minn. Mar. 28, 2016) (rejecting defendant's claim that section 353(b) was vague as applied to a physician writing fraudulent prescriptions); United States v. Travia, 180 F. Supp. 2d 115, 121 (D.D.C. 2001) (upholding criminal complaint charging two individuals with illegally dispensing nitrous oxide in balloons outside a rock concert); United States v. Gen. Nutrition, Inc., 638 F. Supp. 556, 563 (W.D.N.Y. 1986) (denying a motion to dismiss based on a claim that the defendants, who were managers and store clerks at a nutritional supplement outlet, were not on notice that they were violating the FDCA). As one district court explained, "[t]he Act provides that '[a]ny person' who violates section 331 shall be liable. Although the government has cited a number of cases supporting prosecution under the Act of lower level corporate employees, it is unnecessary to go beyond the plain language of the statute. 'Any' means any." Id.; Travia, 180 F. Supp. 2d at 121 ("[T]here is nothing in the FDCA's broad language that limits its coverage to professionals such as physicians, pharmacists, or commercial manufacturers.").

By stark contrast, this Court's Order applies an overly restrictive and illogical meaning to the term "dispensing" in the FDCA that is in direct contravention to the statute's protective purpose and the Supreme Court's broad interpretation of the FDCA's reach. In reaching its conclusion that the defendants could not be "dispensing" drugs under the FDCA because they are "checking pharmacists," the Order relies on a medical dictionary to interpret the act of dispensing as when a pharmacist "fill[s] a medical prescription." Order at 8 (brackets in original) (citing Stedman's Medical Dictionary (28th ed. 2014).[3] The Order then further narrows the assumed scope of the statute by construing "filling" as being limited solely to the act of putting together the prescription, a construction for which it cites no authority.[4] Id. at 8.

[3] The Order seeks support by way of analogy to the case, Commonwealth v. Brown, 925 N.E.2d 845 (Mass. 2010). In Brown, the Massachusetts Supreme Judicial Court concluded that the term "dispensing" in Section 32 of Chapter 94C of the General Laws of Massachusetts only referred to "the act of a physician acting in an authorized manner." Id. at 857. The court found that where a physician "ceases to act as a physician" and delivers drugs pursuant to an invalid prescription, "the physician has devolved into a 'pusher'," who has committed the crime of distribution. Id. By defining "dispensing" as necessarily an authorized act of delivering drugs, the Brown court concludes that one can almost never illegally dispense under Chapter 94C. Id. The effect of the Brown decision was largely to write the term "dispensing" out of the statutory language of the state drug laws.

Relying on Brown as an interpretation of the term "dispensing" in the FDCA is wholly misplaced, and directly conflicts with decades of well-established federal court precedent interpreting the FDCA and the Controlled Substances Act. See United States v. Limberopoulos, 26 F.3d 245, 249 (1st Cir. 1994) (finding that the language of the federal drug laws and "well-established case law mak[e] clear that the statute applies to a pharmacist's (or physician's) drug-dispensing activities so long as they fall outside the usual course of professional practice"); see also Ikejiani, 630 Fed. Appx. at 937 (finding that the term "dispensing" as used in the FDCA applies to wholesale sales by a pharmacist without a prescription); United States v. Williams, 549 Fed. Appx. 813, 821 (10th Cir. 2013) (affirming verdict against pharmacist for dispensing drugs without a valid prescription under the FDCA and the Controlled Substances Act); United States v. Jackson, 576 F.2d 46, 50 (5th Cir. 1978) (affirming conviction for unlawfully dispensing controlled substances where doctor wrote invalid prescriptions for 5,000 patients in four months); Brown v. United States, 250 F.2d 745, 747 (5th Cir. 1958) (affirming FDCA conviction of doctor for dispensing 3,000 tablets without valid prescriptions); United States v. 2600 State Drugs, Inc., 235 F.2d 913, 914 (7th Cir. 1956) (holding evidence was sufficient to find under the FDCA that pharmacist was guilty of dispensing drugs without a valid prescription).

[4] A plainer reading of the term, and one consistent with Massachusetts regulations, would include all aspects of filling a prescription, including the compounding, packaging, and labelling of a drug, as well as the verification check by a pharmacist. See e.g., 247 Mass. Code Regs. 2.00 (defining the word "dispensing").

But the Order's dispensing interpretation would not cover the conduct found violative by other courts around the country, such as that at issue in Ikejiani (wholesale pharmacist), Arlen (bodybuilder selling steroids), De Freese (physician selling drugs in bulk for resale), Oz (physician writing fraudulent prescriptions for an Internet pharmacy), Travia (two individuals selling nitrous oxide in balloons outside a rock concert), or Gen. Nutrition, Inc. (manager and store clerk at a nutritional supplement store). If the FDCA dispensing language has been held to apply to defendants in these cases, it should also surely apply to the practice here of licensed pharmacists (in fact, the only pharmacists) verifying drug orders compiled by order processing support personnel at NECC, and approving them for packaging and shipment. The Order's conclusion that the defendants could not as a legal matter have been dispensing drugs at NECC is simply inconsistent with a body of Supreme Court and other case law interpreting the FDCA.

2. The Order's Dispensing Interpretation Is Also Inconsistent with the Plain Meaning of the Term Defined by Pharmacy Regulations and Common Industry Practice.

Massachusetts pharmacy regulations define dispensing as "the physical act of delivering a drug, chemical, device or combination thereof to an ultimate user pursuant to a lawful order of a practitioner…including *the utilization of the professional judgment of the pharmacist* and the packaging, labeling, or compounding necessary to prepare the drug, chemical, or device for delivery." 247 Mass. Code Regs. 2.00 (emphasis added). Dispensing is not limited to merely "filling" an order, that is, putting pills in a bottle, but rather includes all aspects of preparing a prescription drug for delivery, including packaging, labeling, and verification by a licensed pharmacist.

Moreover, it is common practice in the industry for pharmacists to rely on the work of pharmacy technicians or other pharmacy support personnel to fill prescription drug orders. In such circumstances, the pharmacist must serve as a check to verify the prescription order is correctly filled prior to dispensing it. See 247 Mass. Code Regs. 9.06 ("A prescription written by a practitioner may be filled *only* if the pharmacist called upon to fill such prescription, in the exercise of that pharmacist's personal judgment, determines that…[t]he prescription is issued pursuant to a valid patient/practitioner relationship and for a legitimate medical purpose….") (emphasis added); see also, United States v. Green, 818 F.3d 1258, 1269 (11th Cir. 2016) (noting testimony of pharmacy expert explaining that "while pharmacy technicians may assist pharmacists with certain routine tasks, pharmacy technicians may not themselves fill or dispense prescriptions"); Nemec v. Wal-Mart Assoc., Inc., 2015 WL 8492040, at *2 (D. Minn. Dec. 10, 2015) (describing Wal-Mart's standard operating procedure which provides that medication bottles are filled by pharmacy technicians but verified by a pharmacist); Flood v. Univ. of Md. Med. Sys., 2014 WL 7363237, at *1 (D. Md. Dec. 23, 2014) ("A pharmacist is required to verify each prescription before it is filled by a pharmacy technician and medication cannot leave a pharmacy unless a pharmacist verifies that a prescription is properly filled."). The pharmacist's act of checking a prescription drug order and verifying its accuracy is an essential part of the act of "dispensing," since only a pharmacist is licensed to do so.

In this case, the defendants were the only licensed pharmacists verifying the drug orders filled by pharmacy technicians and other staff. In that role, the defendants utilized their professional judgment as pharmacists in approving drug orders for shipment to NECC's customers and indicating their decisions by signing forms entitled, "Pharmacist's Rx Order Verification Sheets." It is for this precise reason that NECC had pharmacists employed in the position of checking the orders after they were compiled but before they were packaged for shipment. Their checking and approval of orders, actions similarly performed by licensed pharmacists in pharmacies throughout the country every day, fall squarely within the plain meaning of the term "dispensing" as defined in pharmacy regulations and used in the industry. Accordingly, the Order's narrow interpretation in this case is categorically wrong.

3. The Order's Dispensing Interpretation Endangers Public Health.

If allowed to stand, the Order's limited interpretation of "dispensing" endangers the public health and leads to nonsensical results in the enforcement of the FDCA. The Order, as written, allows licensed pharmacists who serve as the final (and only licensed) approval of the shipment of prescription drugs prior to their entry into interstate commerce to escape any criminal liability at all. Applying the Order's interpretation of dispensing leads to the result that only the NECC processing staff (who were not even necessarily pharmacy technicians) who pulled the pre-filled vials of medication off the stock shelves would be the ones considered to be dispensing drugs and presumably accountable under the FDCA. But see United States v. Lovern, 590 F.3d 1095, 1105 (10th Cir. 2009) (finding that a low-level employee with no medical education that performed "only menial computer tasks" including printing prescription labels could not be held to have dispensed medication without a valid prescription). Moreover, pharmacists, such as the defendants, who did have licenses and were responsible for the work of the pharmacy support personnel, could claim a bar to prosecution because they were not the ones to physically pull the drugs off the shelves, and they merely checked the orders before shipment. Such an anomalous result under the FDCA should not stand.

B. Even Under the Order's Overly Narrow "Dispensing" Interpretation, a Jury Could Still Find the Defendants Were Aiding and Abetting the Dispensing of Misbranded Drugs.

In addition to the substantive crimes, the defendants are also charged in the Indictment with aiding and abetting the dispensing of misbranded drugs with the intent to defraud or mislead. The Indictment specifically cites Section 2 of Title 18 of the United States Code in the counts the Court dismissed. Indictment at 59. But the Order does not address this point, and is silent as to how, as a matter of law, the defendants could not be culpable under the FDCA for having aided and abetted the dispensing of misbranded drugs by approving orders of prescription drugs to be shipped under fictitious names.

In the context of a corporation distributing misbranded drugs, "a corporation may commit an offense and all persons who aid and abet its commission are equally guilty." Dotterweich, 320 U.S. at 284. Those who are not even practitioners can be found guilty of aiding and abetting the distribution of misbranded drugs in violation of the FDCA. For example, in United States v. Lovin, 2008 WL 4492616, at *1 (S.D. Cal. Sept. 29, 2008), the defendant operated an affiliated marketing website for an Internet pharmacy operation that dispensed drugs without valid prescriptions. The defendant's website marketed drugs for sale, and directed customers to merchant websites where they purchased drugs "all before the doctors or pharmacists became involved." Id. at 5. In denying the defendant's motion to dismiss the indictment, the district court noted that courts have upheld convictions of non-practitioners for aiding and abetting the distribution of drugs without valid prescriptions. Id. at 4 (citing cases); see also United States v. Carlson, 810 F.3d 544, 555 (8th Cir. 2016) (affirming conviction of store clerk for aiding and abetting the distribution of misbranded drugs where clerk sold drugs to undercover agents). United States v. Smith, 573 F.3d 639, 643-44 (8th Cir. 2009) (affirming convictions of businessman who operated Internet pharmacy site for aiding and abetting the introduction of misbranded drugs where company shipped 72,000 orders of drugs without valid prescriptions). Of course, here the defendants were licensed pharmacists.

To convict on a theory of aiding and abetting, the government must prove that (i) someone else committed the charged crime; and (ii) the defendant consciously shared the other person's knowledge, intended to help, and took part in the endeavor, seeking to make it succeed. Pattern Criminal Jury Instructions for the District Courts of the First Circuit (D. Maine 2015 Revisions), Instruction No. 4.18.02(a). The government would present evidence at trial that easily satisfies these two elements with respect to the defendants. First, the evidence would show that NECC dispensed drugs without valid prescriptions, and that the defendants were aware of this practice. Any reasonable person – let alone a trained pharmacist – would know that sending prescription drugs to "patients" named L.L. Bean, Filet O' Fish, and Wonder Woman was illegal. In fact, the government expects to introduce evidence that defendant Thomas specifically raised questions to defendant Stepanets about the legality of approving the orders, and yet continued to do it. Second, the defendants took affirmative steps to further the offenses. The defendants checked and approved the drug orders to be shipped to customers for use on patients, indicating their approval on forms entitled, "Pharmacist's Rx Order Verification Sheet." Following the defendants' approval, the drugs were given to NECC's shipping employees who packaged the drugs for shipment to customers. Because the defendants played an indispensable role in the process, that is, the approval of a licensed pharmacist for the drugs to be dispensed, a rational juror could clearly find that they aided and abetted the unlawful transaction. Accordingly, the Order should be reconsidered for this additional reason.

II. To the Extent that the Order Concluded that Defendants Were Not Dispensing as a Matter of Fact, the Court Erred.

A. The Court Erred by Deciding Mixed Questions of Law and Fact that Should Have Been Reserved for the Jury at Trial.

At the heart of this Court's Order is the central question of whether the defendants' conduct amounted to dispensing under the FDCA. While a court may properly reach questions of statutory interpretation at any point in the proceedings, to answer this question the Court must first determine what the defendants' conduct *actually was*. But when a "pretrial motion raises questions of fact which are intertwined with issues involving the merits, a determination of that matter must be deferred until trial." United States v. Vincenzi, 1988 WL 98634, at *3 (D. Mass. Feb. 16, 1998);

see also United States v. Marbelt, 129 F. Supp. 2d 49, 56 (D. Mass. 2000) (holding that where "the questions involved in the motion to dismiss the indictment involve mixed questions of fact and law, properly decided at trial, a motion to dismiss must be denied"). A challenge to the sufficiency of an indictment is not an opportunity to determine the sufficiency of the evidence at trial. United States v. Stewart, 744 F.3d 17, 21 (1st Cir. 2014).

Yet after describing the proper standard by which to judge the sufficiency of an indictment, the remainder of the Order addresses questions of fact. The Order is based in large part on inferences (put forth by the defendants) as to the nature of the defendants' conduct at NECC. The Indictment alleges the defendants were "checking orders prior to shipment." Indictment at 4-5. The Order infers this language to mean that the defendants' responsibilities were "incidental to the distribution of prescribed drugs," "checking a package," akin to "picking it up for delivery," or "matching orders to packages prior to their being shipped." Order at 11-12. These are all factual conclusions (which government vigorously disputes), and are improper at this stage of the case. The Indictment does not allege the particulars of the defendants' responsibilities – nor was it required to do so. By assuming its own conclusion as to the nature of the defendants' roles – or adopting the defense's interpretation of the same – the Order improperly reaches a legal conclusion based on incorrect underlying factual determinations. Such determinations are the province of a jury at trial. "A motion to dismiss an indictment is not a device for a summary trial of the evidence, but rather it is directed only to the question of the validity of the indictment on its face." Vincenzi, 1988 WL 98634, at *3. Questions regarding the specifics of the defendants' roles at NECC should be determined at trial in the context of all of the evidence, not via a defense motion and version of the facts challenging the sufficiency of the indictment. For these additional reasons, the Court should reconsider its Order.

B. The Court Erred by Reaching Incomplete and Inaccurate Factual Determinations.

The principle underlying the general rule assigning questions of fact for determination at trial is premised on the notion that a Court should not substitute its own view based on an incomplete account of what has transpired with that of the grand jury that benefits from understanding the entire investigation. See Whitehouse v. U.S. District Court, 53 F.3d 1349, 1360 (1st Cir. 1995) ("When a federal court uses its supervisory power to dismiss an indictment it directly encroaches upon the fundamental role of the grand jury."). While the government maintains that the appropriate venue for the determination of factual questions and the sufficiency of the evidence is at trial, it believes it important to note some differences between the facts assumed or concluded in the Order, and the evidence that the government expects to introduce at trial.

First, the Order infers from the Indictment's allegations that the defendants' work was "incidental to the distribution of a prescribed drug," such as "checking a package" or akin to "picking it up for delivery." Order at 11. This is simply incorrect. As described above, the defendants' checking role within the NECC dispensing process was much more integral and important than that. Under Massachusetts law, only licensed pharmacists can dispense prescription medication. The NECC order processing staff and employees, who processed the orders, pulled the pre-filled drugs from the stock bins, created the "prescriptions" in NECC's electronic database, and generated the shipping documents, were not licensed to dispense drugs. For the counts charged, the defendants were the *only* licensed pharmacists to verify and approve the orders of prescription drugs for shipment to customers. The defendants were acting in their official capacities as licensed pharmacists, and verified their work on forms entitled, "Pharmacist's Rx Order Verification Sheet." Thus, it is for this reason that NECC hired only licensed pharmacists to fill this role and did not rely on the non-practitioner employees in the packing/shipping area to do it. Verification of work done by pharmacy support personnel is precisely the work of licensed pharmacists in the dispensing process, and falls within the plain meaning of "checking orders prior to shipment" as alleged in the Indictment. To suggest instead that the defendants are mere shipping clerks performing ministerial duties "incidental to distribution of a prescribed drug" is incorrect.

Second, the Order suggests that the defendants were "participating in the filling of a prescription that she had never approved (or is even alleged to have seen)…." Order at 12. Once again, this factual assertion is erroneous. The defendants' role as checking pharmacists was to review the Prescription Order Forms (with the clearly fake names on them) to ensure that the drugs provided by the NECC staff were correct in name, amount, and dosage forms, and being shipped to the correct customer. The defendants, as licensed pharmacists, were verifying and approving the orders for distribution and shipment. No one else in the NECC order processing chain had the authority to do so on the counts charged. Moreover, the work of verifying the drug orders is precisely the work that pharmacists do throughout the industry. It is the common practice of licensed pharmacists to verify the work of pharmacy technicians who put together drug orders for customers. Moreover, the defendants were aware that they were shipping drugs to fictitious patients. Defendant Thomas specifically raised questions to defendant Stepanets about the legality of approving drugs for shipment to patients named L.L. Bean and Filet O'Fish. The Order's conclusion that the Indictment is holding the defendants liable for work that someone else did is categorically misplaced. The government is not, as the Court seems to be wary of, charging a mailman who unknowingly moved a package from point A to point B. Instead, the Indictment alleges that these three pharmacists, who by law are entrusted with gatekeeping functions, and who possess the requisite training to evaluate the validity of prescriptions, knowingly approved shipments of drugs pursuant to invalid prescriptions in violation of the law. Accordingly, the Order should be reconsidered for this reason as well.

III. To the Extent that the Order Suggests Prosecution of the Defendants Under the FDCA Is an Overreach, the Court Erred.

The conduct at issue in this case – the unlawful dispensing of prescription medication – is precisely the conduct that the FDCA proscribes. This is not a question of whether a fish qualifies as a tangible object, or hosting a reception at a governor's mansion is a corrupt official act. The government does not seek to apply the FDCA to some obscure set of actions outside of its scope. The defendants are licensed pharmacists who have been charged with dispensing medication without valid prescriptions. They did so in a pharmacy that flagrantly ignored pharmacy rules and standards. The government seeks to apply the FDCA for the very purpose it was enacted – to protect consumers against the dangers of improper dispensation of prescription medication, and to prosecute those responsible for endangering the public health. This is not a situation where the FDCA has been cut loose from its public health mooring. See Yates v. United States, 135 S. Ct. 1074, 1079 (2015) (finding that to define a fish as a "tangible object" under the Sarbanes-Oxley Act would cut it loose from its "financial-fraud mooring"). The Order's citations to Yates and McDonnell v. United States, 136 S. Ct. 2355 (2016), are surprising and misplaced.

Nor is this case a question of vagueness, as the Court suggested in its Order. Order at 11. Contrary to the defendants' repeated assertions on this point, "it is clear what the [Act] as a whole prohibits." Grayned v. City of Rockford, 408 U.S. 104, 110 (1972). Moreover, the Act "gives fair notice to those to whom (it) is directed." Id. at 112.[5] The Act prohibits, among many other things, dispensing or causing to be dispensed and introduced into interstate commerce drugs without a

[5] Moreover, as the Court noted, "[t]he government (as best I can determine) is correct in stating that no court has upheld a generic vagueness challenge to the dispensing provision or other prohibitions of the FFDCA." Order at 10 n.5.

valid prescription. It is directed, among others, at those who cause prescription drugs to enter interstate commerce without a valid prescription. While the defendants argue that the FDCA was not intended to reach their actions because of their purported lowly positions in NECC's organizational framework, this is simply irrelevant to application of the FDCA. The FDCA regulates conduct, not job titles. See Gen. Nutrition, Inc., 638 F. Supp. at 563 (denying motion to dismiss filed by low-level employees, finding that "[t]heir respective positions do not excuse their alleged conduct"). Because the FDCA directly applies to the defendants' conduct of causing drugs to be dispensed without valid prescriptions, the Court should reconsider its Order.

IV. **To the Extent that the Court Held that the Indictment Failed to State a Claim or was in Another Way Deficient, the Court Erred.**

The Court erred in finding these counts in the Indictment were deficient. In assessing the sufficiency of an indictment, a court must determine whether the indictment "contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and, second, enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense." Hamling v. United States, 418 U.S. 87, 117 (1974). The First Circuit has held that indictments are sufficient where they meet these requirements and are specific enough to inform the defendant of the nature of the charges. United States v. Geurrier, 669 F.3d 1, 3 (1st Cir. 2011). The Indictment in this case plainly meets these requirements, and thus, the dismissal of these charges was in error.

First, the Indictment contains the elements of the offense and fairly informs the defendants of the charges against which they must defend. See Indictment at 56. The Indictment closely tracks the wording of the FDCA, and includes all of the elements of the offense. See e.g., Arlen, 947 F.2d at 145 ("[T]he language of the statute may guarantee sufficiency if all required elements are included in the statutory language." (internal citation omitted)). It goes further and provides the defendants with the specifics as to each order for which they are charged with misbranding. The Indictment also provides notice to the defendants of the enhanced penalties they would face upon conviction of these offenses.

Second, the Indictment enabled the defendants to enter a plea without fear of double jeopardy as to the acts alleged. Contrary to the Court's description of the Indictment as "sparse," Order at 6, the Indictment in fact lays out a detailed, three-page table showing the exact drug orders related to each charge. See Indictment at 57-59. The table includes the date of each shipment, the description of exactly what each shipment contained, the location where the shipment was sent, the fake patient names listed on each prescription, and the names of the defendants charged for each of the shipments. Id.

Third, reading the charging language and the associated table together, the government presented a clear statement of the essential facts constituting the offenses charged. The Indictment states that the defendants caused to be dispensed the drugs listed in the associated table, and that each instance represents a separate charge. It is not "tautological" to say that the defendants are adequately charged with dispensing because the Indictment states that they did so, and provides the specific items they dispensed and the relevant dates and locations for the shipments. Quite simply, that is the purpose of the Indictment, and it satisfies the test of sufficiency. See United States v. Savarese, 686 F.3d 1, 7 (1st Cir. 2012) (noting that "the question is not whether the government has presented enough evidence to support the charge, but solely whether the allegations in the indictment are sufficient to apprise the defendant of the charged offense"). "It describes the statutorily defined elements of the charged crimes, the general factual scenario on which the charges rest, and the connection between those elements and facts." Id. at 8. The Indictment is not required to do more.

Because the Indictment was sufficient, and because the Court's decision was based on a manifest error of law, the Court should reconsider its order granting the defendants' motions to dismiss.

CONCLUSION

For the above reasons and those set out in the government's original oppositions (Doc. Nos. 381, 461), the United States respectfully requests that the Court reconsider its October 4, 2016 Memorandum and Order on Defendants' Motions to Dismiss (Doc. No. 675) and its October 4 electronic order (Doc. No 678), and reinstate Counts 104-107 and 108-109 as they relate to Ms. Chin and Ms. Thomas, and Counts 96-98, 101-103, and 108, relating to Ms. Stepanets.

Respectfully submitted,

WILLIAM D. WEINREB
ATTORNEY FOR THE UNITED STATES
Acting Under Authority Conferred by 28 U.S.C. § 515

By: /s/ George P. Varghese
AMANDA P.M. STRACHAN
BBO # 641108
GEORGE P. VARGHESE
Assistant United States Attorneys
John J. Moakley United States Courthouse
One Courthouse Way, Suite 9200
Boston, Massachusetts 02210
(617) 748-3100
amanda.strachan@usdoj.gov
george.varghese@usdoj.gov

Dated: October 28, 2016

Certificate of Service

I hereby certify that the foregoing documents filed through the ECF system will be sent electronically to counsel for the defendants, who are registered participants as identified on the Notice of Electronic Filing (NEF).

By: /s/ George P. Varghese
GEORGE P. VARGHESE
Assistant United States Attorney

Dated: October 28, 2016